



GEORGIA MEDICAID FEE-FOR-SERVICE ONCOLOGY, ORAL - LUNG PA SUMMARY

Preferred	Non-Preferred
Alecensa (alectinib) Alunbrig (brigatinib) Gilotrif (afatinib) Iressa (gefitinib) Lorbrena (lorlatinib) Tagrisso (osimertinib) Tarceva (erlotinib) Vizimpro (dacomitinib) Xalkori (crizotinib) Zykadia (ceritinib)	N/A

LENGTH OF AUTHORIZATION: 1 Year

NOTE: Special consideration taken for members with stage IV advanced metastatic cancer.

PA CRITERIA:

Alecensa

- ❖ Approvable for members with a diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC) when the member has tested positive for anaplastic lymphoma kinase (ALK) NSCLC as detected by a Food and Drug Administration (FDA)-approved test or other validated test performed in a Clinical Laboratory Improvement Amendments (CLIA)-approved facility.

Alunbrig

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK NSCLC as detected by a FDA-approved test or other validated test performed in a CLIA-approved facility and when the member has disease progression on or is intolerant to crizotinib (Xalkori).

Gilotrif

- ❖ Approvable for members with a diagnosis of advanced or metastatic non-squamous NSCLC when the member has tested positive for epidermal growth factor receptor (EGFR) mutations, such as S768I, L861Q, G719X, exon 19 deletion or exon 21 (L858R) substitution, as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility and when the medication is being used as first-line TKI therapy.
- ❖ Approvable for members with a diagnosis of advanced or metastatic squamous NSCLC when member has disease progression on or after platinum-based chemotherapy.
- ❖ Approvable for members with a diagnosis of recurrent, unresectable or metastatic squamous cell carcinoma of head or neck when member has disease progression on or after platinum-based chemotherapy.



Iressa

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility and when the medication is being used as first-line TKI therapy.

Lorbrena

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK NSCLC as detected by a FDA-approved test or other validated test performed in a CLIA-approved facility and when the member has disease progression on or is intolerant to crizotinib (Xalkori) and at least one other ALK inhibitor (Alecensa, Alunbrig or Zykadia) or when the member has disease progression on or is intolerant to alectinib (Alecensa) or ceritinib (Zykadia) as the first ALK inhibitor therapy for advanced or metastatic disease.

Tagrisso

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR T790M mutation as detected by a FDA-approved test or other validated test performed in a CLIA-approved facility and when the member has disease progression on or after EGFR tyrosine kinase inhibitor (TKI) therapy (erlotinib [Tarceva], afatinib [Gilotrif], gefitinib [Iressa]).
- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility and when the medication is being used as first-line TKI therapy.
- ❖ Approvable for members with progressive leptomeningeal disease.

Tarceva

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility.
- ❖ Approvable for members with a diagnosis of locally advanced, unresectable or metastatic pancreatic cancer when used in combination with gemcitabine.
- ❖ Approvable for members with progressive leptomeningeal disease.

Vizimpro

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility and when the medication is being used as first-line TKI therapy.

Xalkori

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK or ROS1 NSCLC as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility.



Zykadia

- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ALK NSCLC as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility.
- ❖ Approvable for members with a diagnosis of advanced or metastatic NSCLC when the member has tested positive for ROS1 NSCLC as detected by an FDA-approved test or other validated test performed in a CLIA-approved facility and when the medication is being used as first-line TKI therapy.
- ❖ In addition for the tablet formulation, prescriber must submit a written letter of medical necessity stating the reasons the capsule formulation is not appropriate for the member.

EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827**.

PREFERRED DRUG LIST:

- For online access to the Preferred Drug List (PDL), please go to <http://dch.georgia.gov/preferred-drug-lists>.

PA and APPEAL PROCESS:

- For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

- For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Pharmacy and click on [Other Documents](#), then select the most recent quarters QLL List.